UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/350,899	07/12/99	TSUJI K	029650-080

021839 HM12/1003
BURNS DOANE SWECKER & MATHIS L L P
POST OFFICE BOX 1404
ALEXANDRIA VA 22313-1404

EXAMINER	
CANELLA,K	
ART UNIT	**PAPER NUMBER**
1642	3

DATE MAILED: 10/03/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/350,899	Tsuji et al
Examiner	**Group Art Unit**
Karen Canella	1642

☐ Responsive to communication(s) filed on _____

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3 months* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *10-15* is/are pending in the applicat

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *10-15* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 1, 2

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

DETAILED ACTION

1. Claims 1-9 are canceled. Claims 10-15 are added and examined on the merits.

Drawings

2. The drawings are objected to because of the reasons set forth on the enclosed PTO-948 form. Correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 10-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 10 recites "a molecular weight of 200kD or more (SDS-PAGE)".

Claim 10 recites: "(SDS-PAGE)". A reference to the method of moecular weight determination should be incorporated directly into the claim language as ---a molecular weight of 200kD or more as determined by SDS-PAGE.---

Claim 10 recites: "a molecular weight of 200kD or more". This is indefinite in that the claim does not state if the molecular weight was obtained under reducing or non-reducing conditions. Proteins can exhibit widely differing apparent molecular weight as determined by SDS-PAGE in the absence or presence of thiol groups, therefore the recitation of "molecular weight...(SDS-PAGE)" without further qualifiers, does not set the metes and bounds of claim 10.

5. Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are objected to as being indefinite in the use of antibody designations TRD-

L1, 2 and 3 as the sole means of identifying the claimed hybridomas. The use of laboratory designations only to identify a particular antibody/cell line renders the claims indefinite because different laboratories may use the same laboratory designations to define completely distinct hybridomas and antibodies. Amendment of the claims to include the depository accession number of the mAb or hybridoma is required, because deposit accession numbers are unique identifiers which unambiguously define a given hybridoma and/or monoclonal antibody.

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claim 14 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention because the specification does not provide evidence that the claimed biological materials are (1) known and readily available to the public; (2) reproducible from the written description.. Claim 14 is drawn to an immunoassay method wherein the claimed antibodies are produced by the hybridoma cell lines TRD-L1, TRD-L2, TRD-L3. The specification states that the hybridoma cell lines have been designated FERM P-14878, FERM P-14879 and FERM P-14880, respectively and have been "transferred to authority on Feb., 8, 1996 under Budapest Treaty" (pg 3, line 24 to pg 4, line 10). This statement is insufficient assurance that all of the conditions of 37 CRF sections 1.801 through 1.809 have been met. If the deposit was made under the provisions of the Budapest Treaty, filing of an affidavit or declaration by applicant, assignees or a statement by an attorney of record over his or her signature and registration number stating that the deposit has

been accepted by an International Depository Authority under the provisions of the Budapest Treaty, that all restrictions upon public access to the deposits will be irrevocably removed upon grant of a patent on this application and that the deposit will be replaced if viable samples cannot be dispensed by the depository is required. This requirement is necessary when a deposit is made under the provision of the Budapest Treaty as the Treaty leaves these specific matters to the discretion of each State. Additionally, amendment of the specification to recite the dates of the deposit, the complete name and address of the depository, and the accession number of the deposited cell line is required.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 10-12 are rejected under 35 U.S.C. 102(b) as being anticipated by either Yang et al (IDS, Paper No. 2) or Ten et al (Anticancer Research, 1986, vol. 6, pp. 983-988). Claims 10-12 are drawn to a glycoprotein antigen having a molecular weight of 200kD, which is expressed and secreted from human lung adenocarcinoma and a method of detecting human lung adenocarcinoma comprising contacting a sample with a monoclonal antibody which binds to said glycoprotein antigen. Further embodiments include the reaction of the glycoprotein antigen with the lectins MAA and PNA, but no reaction with the lectins GNA, SNA and DSA. Yang et al disclose glycoprotein molecules of about 200kD which are synthesized by lung adenocarcinoma cells and a method of assaying for these antigens by contacting a sample with a mucin-specific monoclonal antibody. Ten et al disclose ADCP as a dimeric glycoprotein of 200kD, the soluble form of which is decreased in cancers of the lung. Yang et al or Ten et al do not disclose the

reactivity of the synthesized glycoprotein molecules with the specific lectins of MAA, PNA. However, the claimed glycoproteins appears to be the same as the prior art glycoproteins, and therefore would have the same properties of binding to the lectins MAA and PNA. The office does not have the facilities and resources to provide the factual evidence needed in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed product is different from those taught by the prior art. See In re Best 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989).

10. Claims 10-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Werner et al (IDS, Paper No. 2) as evidenced by Eskelin et al (Anticancer Research, 1994, Vol. 14, pp. 699-703). Claims 10-12 are drawn to a glycoprotein antigen having a molecular weight of 200kD, which is expressed and secreted from human lung adenocarcinoma and a method of detecting human lung adenocarcinoma comprising contacting a sample with a monoclonal antibody which binds to said glycoprotein antigen. Further embodiments include the reaction of the glycoprotein antigen with the lectins MAA and PNA, but no reaction with the lectins GNA, SNA and DSA. Werner et al disclose the TAG-12 antigen having a molecular weight of about 200kD, expressed by lung adenocarcinomas, and a method of detecting lung adenocarcinoma by contacting a sample with a monoclonal antibody which binds to the TAG-12 antigen. Eskelinen et al disclose that the TAG-12 is a secreted antigen. Werner et al do not disclose the reaction of TAG-12 with the specific lectins MAA and PNA but do disclose that TAG-12 is purified by lectin affinity chromatography. Therefore, the claimed glycoproteins appears to be the same as the prior art glycoproteins and would have the same properties as binding to the lectins MAA and PNA. The office does not have the facilities and resources to provide the factual evidence needed in order to establish that the product of the prior art does not possess the same material, structural and

functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed product is different from those taught by the prior art. See In re Best 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989).

11. Claim 10-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Taniguchi et al (IDS, Paper No. 2). Claims 10-13 are drawn to a glycoprotein antigen having a molecular weight of 200kD, which is expressed and secreted from human lung adenocarcinoma and a method of detecting human lung adenocarcinoma comprising contacting a sample with a monoclonal antibody of the IgM class which binds to said glycoprotein antigen. Further embodiments include the reaction of the glycoprotein antigen with the lectins MAA and PNA, but no reaction with the lectins GNA, SNA and DSA. Taniguchi et al disclose an antigen secreted by a human lung adenocarcinoma line, having a molecular weight of about 200kD, and a method for detecting lung squamous cell carcinoma comprising contacting a sample with an antigen specific monoclonal antibody of the IgM class. Taniguichi does not disclose reactivity of the antigen with lectins, but for the reasons set forth in the above 102(b) rejection absent a showing of results to the contrary, the antigen could be identical to the antigen of the instant invention. See: In re Best 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989).

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

14. Claims 10-12 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Taniguchi et al in light of Wright (USP 5314996). Claims 1-12 and 15 are drawn to are drawn to a glycoprotein antigen having a molecular weight of 200kD, which is expressed and secreted from human lung adenocarcinoma and a method of detecting human lung adenocarcinoma comprising contacting a sample with a Fab or F(ab)2 or Fv fragment of a monoclonal antibody which binds to said glycoprotein antigen. Further embodiments include the reaction of the glycoprotein antigen with the lectins MAA and PNA, but no reaction with the lectins GNA, SNA and DSA. Taniguchi et al teach a secreted antigen from lung adenocarcinoma having a molecular weight of 200kD in addition to a method of detecting lung cancer comprising contacting a sample with an IgM monoclonal antibody specific to the secreted antigen. Taniguchi et al do not teach a method of detecting lung cancer comprising contacting a sample with a Fab or F(ab)2 or Fv fragment of a monoclonal antibody which binds to said glycoprotein antigen. Wright teaches a method of detecting prostate carcinoma comprising contacting a Fab or F(ab)2 or Fv fragment of a monoclonal antibody to a sample . It would have been *prima facia* obvious to one of ordinary skill in the art at the time the claimed invention was made to use the Fab or F(ab)2 or Fv fragment of a monoclonal antibody to the antigen taught by Taniguchi in a method of detecting the lung adenocarcinoma. One of ordinary skill in the art would have been motivated to do so with a

reasonable expectation of success by the teachings of Wright on the success of using a Fab fragment of a prostate antigen-specific monoclonal antibody in the detection of prostate cancer.

Double Patenting

15. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

16. Claims 12-15 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 4-8 of U.S. Patent No. 6,015,680. Although the conflicting claims are not identical, they are not patentably distinct from each other because the are drawn to an immunoassay method for the detection of human lung adenocarcinoma comprising the use of the idntical monoclonal antibodies of the instant invention. The instant specification states on pg. 4 that the hybridoma cell lines TRD-L1, TRD-L2 and TRD-L3 of claim are identical to the hybridoma cell lines FERM BP-5383, FERM BP-14879 and FERM BP-14880.

Conclusion

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Canella whose telephone number is (703) 308-8362. The examiner

can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Karen A. Canella, Ph.D.
Patent Examiner, Group 1642
September 29, 2000

GEETHA P. BANS
PRIMARY EXAMI